

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

# IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO:  
ALL CLASS ACTIONS

Judge Patti B. Saris

**TRACK 1 DEFENDANTS' NOTICE OF SUPPORTING AUTHORITY  
REGARDING CONGRESSIONAL STATUTORY ADOPTION OF AWP IN 1997**

During the hearing on May 23, 2006, the Court requested citations to the legislative history regarding Congress' statutory adoption of the term "average wholesale price" in 1997. In response to those questions, Track 1 Defendants hereby bring to the Court's attention material – already in the record – regarding congressional intent in 1997.

- **The 1997 Statute:**

if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part . . . the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.

Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4566(a) (1997) (codified as 42 U.S.C. § 1395u(o)(1)) (Fowler Decl. Ex. 44). References to the "Fowler Decl." refer to the Exhibits filed on March 15, 2006 in support of the Track 1 Defendants' Motion for Summary Judgment. (For the Court's convenience, Fowler Decl Ex. 44 is attached hereto as Ex. A.)

- **House Committee Report:**

*Reason for Change.* The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists

pay to acquire such pharmaceuticals. For example, the Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs. *The Committee intends that the Secretary, in determining the average wholesale price, should take into consideration commercially available information including such information as may be published or reported in various commercial reporting services.*

Balanced Budget Act of 1997, Report of the Comm. on the Budget of the House of Representatives, H.R. Rep. No. 105-149, at 1354 (1997) (Fowler Decl. Ex. 42) (emphasis added) (For the Court's convenience, attached hereto as Ex. B).

- **Senate Committee Testimony by Secretary of Health and Human Services regarding the Administration's 1997 Proposal, which was rejected by Congress:**

Medicare pays the "average wholesale price" (AWP) for covered drugs. However, the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a "sticker" price set by drug manufacturers and published in several commercial catalogs. . . .

Also, the current payment rules for drugs allow an increase in the AWP even if the cost to the physician remains constant. . . .

Effective January 1, 1998, the Administration's proposal would eliminate the mark-up for drugs by basing Medicare's payment on the provider's acquisition cost of the drug. . . .

Under the proposed policy, physicians would report their acquisition cost for each drug on the claim submitted for reimbursement. Physicians, rather than HCFA, would determine their acquisition cost.

*President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare: Hearings before the Comm. on Finance, U.S. Sen., 105th Cong. 85 (1997) at 265 (responses of Donna E. Shalala, then-Secretary of HHS, to questions from committee members) (Fowler Decl. Ex. 40) (For the Court's convenience, attached hereto as Ex. C).*

- **1999 Report Filed by Secretary of Health and Human Services as Required by 1997 Statute:**

Section 4556(a) of the BBA requires the Secretary, by July 1, 1999, to report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate, the effect, if any, that the new payment limit may have had on the AWP for these drugs and biologicals. The following is that report. . . .

In 1991, we published a final rule to revise the regulations to set payment at the lower of the estimated acquisition cost (EAC) or the AWP. . . .

For the past 13 years, the Office of Inspector General (OIG) has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than the AWP. To address this problem, the President's 1997 budget contained a legislative proposal that would have based payment on the lower of the billed charge or the actual acquisition cost (AAC) for the drug of the physician or supplier billing Medicare. However, as discussed above, in the BBA, Congress rejected this proposal in favor of the current rule, which is to pay based on the lower of the billed charge, or 95 percent of the AWP. . . .

The AWP is not a well-defined concept nor is it regulated in any way.

Donna E. Shalala, then-Secretary of HHS, *Report to Congress, The Average Wholesale Price for Drugs Covered under Medicare* (1999) at 1-2 (Fowler Decl. Ex. 58) (For the Court's convenience, attached hereto as Ex. D).<sup>1</sup>

Respectfully submitted,

THE TRACK 1 DEFENDANTS

By its attorneys,

/s/ John T. Montgomery

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<sup>1</sup> The 1997 legislative history provides the same government understanding of AWP as the administrative record compiled by HCFA in 1991, the congressional record underlying the 2000 moratorium on administrative adjustments to AWP, and the 2003 record relating to the Medicare Modernization Act. For the convenience of the Court, the Track 1 Defendants have prepared a list of those materials and their location in the record. See Ex. E, attached hereto.

**CERTIFICATE OF SERVICE**

I hereby certify that on May 26, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson  
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